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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,404	05/15/2002	Masamichi Okada	Q68135	2114

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Sughrue Mion
2100 Pennsylvania Avenue NW
Washington, DC 20037-3213

EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,404

Applicant(s)

OKADA ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This application is a 371 of PCT/JP00/05074 which claims priority to Japan 11/218309.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for those particular compounds having mGluR1 antagonistic activity disclosed in the specification (see, e.g., page 7 line 21 to page 8 line 2 herein) in the compositions herein, does not reasonably provide enablement for the employment any mGluR1 antagonists in the claimed composition herein.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,

- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

In the instant case, "a mGluR1 antagonist" may encompass any mGluR1 antagonists. However, Applicant's specification provides the experimental results showing that only two particular mGluR1 antagonists, Compounds 1 and 2, are tested for the instant composition. Thus, these examples fail to provide sufficient working examples to support the broad use of any "mGluR1 antagonists" in the claimed composition. Note that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, the instant claims read on the employment of any compounds having mGluR1 antagonistic activity in a pharmaceutical composition useful in treating a neuropathic pain, necessitating one of skill to perform an exhaustive search for the embodiments of "any compounds having mGluR1 antagonistic activity" suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention absent undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "a compound having mGluR1 antagonistic activity" in claim 1 render the claim indefinite since the scope of claims is indefinite as to as to the composition encompassed thereby. Thus, this expression in the claims fail clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fisher et al. (PTO-1449 submitted January 18, 2002).

Fisher et al. discloses that the particular compounds having mGluR1 antagonistic activity in effective amounts are useful in pharmaceutical compositions and treating

neuropathic pain. See abstract, page 60 the left column. Thus, Fisher et al. anticipates claims 1-3.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Neugebauer et al. (PTO-1449 submitted January 18, 2002).

Neugebauer et al. discloses that the particular compounds having mGluR1 antagonistic activity in effective amounts are useful in pharmaceutical compositions and treating neuropathic pain. See abstract, page 272 the left column and page 273 the right column, 4th paragraph (Administration of drugs). Thus, Neugebauer et al. anticipates claims 1-3.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Salt et al. (PTO-1449 submitted January 18, 2002).

Salt et al. discloses that the particular compounds having mGluR1 antagonistic activity in effective amounts are useful in pharmaceutical compositions and treating neuropathic pain. See abstract, page 452 and page 455. Thus, Neugebauer et al. anticipates claims 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fisher et al. (PTO-1449 submitted January 18, 2002), Neugebauer et al. (PTO-1449 submitted January 18, 2002), and Salt et al. (PTO-1449 submitted January 18, 2002).

Fisher et al. discloses the intrathecal administration of a pharmaceutical composition comprising the particular compound having mGluR1 antagonistic activity in effective amounts. See abstract, page 60 the left column.

Neugebauer et al. discloses the administration of a pharmaceutical composition comprising the particular compound having mGluR1 antagonistic activity in effective amounts. See abstract, page 272 the left column and page 273 the right column, 4th paragraph (Administration of drugs).

Salt et al. discloses the administration of a pharmaceutical composition comprising the particular compounds having mGluR1 antagonistic activity in effective amounts. See abstract, page 452 and page 455.

The prior art does not expressly disclose the oral or systemic administration of a pharmaceutical composition comprising the particular compound having mGluR1 antagonistic activity.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to select premenstrual syndrome from the group of disorders including the same to be treated, employing these active compounds.

One having ordinary skill in the art at the time the invention was made would have been motivated to orally or systemically administer a pharmaceutical composition

comprising the particular compound having mGluR1 antagonistic activity because these pharmaceutical compositions comprising active compounds in the prior art are known to be administered broadly. Further, determination of routes of administration from those well known in the art is considered well within the skill of artisan.

Claim Objection

Claim 6 is objected to as being dependent upon a rejected base claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The claimed composition herein employing the specified compound in claim 6 is not seen to be taught or fairly suggested by the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. A. Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
July 16, 2002

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